



# Key issues in the Biotechnology Bill, 2012

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# Introduction

- The Biotechnology Bill, 2012 was published and tabled in parliament 2012
- Since then, parliament has been considering the Bill

# Objectives of Biotechnology Bill

- The Objectives of the Bill are
  - a. To facilitate the safe development and application of modern biotechnology;
  - b. to designate a national focal point, and competent authority;
  - c. to establish national biosafety committee;
  - d. to provide for the establishment of institutional biosafety committees;
  - e. to provide mechanism to regulate research, development and general release of genetically modified organisms and for related matters

# Key issues in the Biotechnology Bill

## Title

- “The National Biotechnology and Biosafety Bill, 2012” on the other hand the Committee proposes the title to be changed to *The Genetically Modified Organisms and Biosafety Bill, 2012.* Bio technology is an extremely wide area which includes medical biotechnology, agriculture biotechnology, industrial biotechnology, environment biotechnology
- However the content of the Bill does not look at Biotechnology and Biosafety.
- It is proposed the Bill be named “*The Genetic Modified Organisms and Products Bill, 2016*”

- The current title of the bill is “the national bio safety act” This is largely misleading. Bio technology is an extremely wide area which includes medical biotechnology, agriculture biotechnology, industrial biotechnology, environment biotechnology
- We propose that the short title be “the Genetic Modified Organisms Act
- The rationale is that the short title should provide a clear description of what the regulation is about.

# KEY CONCERNS OF THE COMMITTEE

- Limited participation contrary to Cartagena Protocol on biosafety, there has been limited awareness, education, participation and availability of information
- Weak criminal sanctions against relating to release and disposal of GMO, harm to the environment
- The need for elaborate safety requirements for gmo laboratories or activities relating to gmo's
- Loss of indigenous species
- The bill did not provide for labeling
- Limited access to information

# Application of the Act

- Under the Bill the Act will apply to research and general release of a GMO but does not apply to use of GMOs for drugs
- This application is narrow and leaves room for manipulation in future.

# Application of the Act

- *The Proposed application is*
  - (a) all activities aimed at research into and the development, importation, exportation and use of Genetic Modification processes;*
  - (b) the import, export, contained use, release or placing on the market of any product of genetically modified product that is likely to have effect on human health, the environment, the economy, national security or social norms and values;*



# Application cont'

*(c) any activity involving molecular engineering technologies such as metabolic engineering, protonomics, metabolomics, nanotechnology, genetic modifications, cloning, DNA-chip technology, bioinformatics and such other technologies as may be declared by the Authority to constitute potentially harmful research or undertakings; (d) all measures aimed at minimizing the impact of Genetic Engineering processes on national security, human health, animals, plants and the environment.*

- *This will enable increase the scope of application of the law for better enforcement*

# Environmental principles

- The bill is silent on application of environmental principles in conducting GMO research and the role of NEMA is not specified.
- The proposal is to introduce environmental principles and enhance the role of NEMA in management and control of GMO research in Uganda

# Environmental principles

*(1) A person doing research, sale, processing, manufacture or dealing with genetically modified products in any way shall comply with environmental principles and safeguards prescribed by the National Environment Management Authority Act and other applicable laws.*

*(2) No Genetically Modified product or organism shall be introduced in Uganda without conducting an Environment Impact Assessment in accordance with the National Environment Management Act.*

*(3) The National Environment Management Authority shall in consultation with the Authority make principles and safeguards for the management, research, introduction into the environment of any genetically modified products or organisms in Uganda*

*(4) For avoidance of doubt, principles and guidelines made in (3) above may provide for offences and other forms of punishment for persons who fail to comply with the guidelines.*

# Regulation of GMOs

- Parliamentary Committee introduced an Authority as an overall body to regulate and licence conduct of GMO research, release, sale, import and export
- This is welcome since it removes a conflict of interest that was created by letting the National Council for Science and Technology be the regulator and the key promoter of research in the country.

# Register of GMOs

- The committee of parliament removes a registrar of GMO and a register of GMOs
- This means we run a risk of not knowing what GMO products are in the country at any one time.
- We propose to reinstate a register of GMOs where all GMO products in the country are registered and should be available to be searched by any member of the public.

# Register of GMOs

- There should be a register of permits issued these include
  1. Permits and licences issued to institutions and labs to do research and
  2. Permits and licences for specific research

This will enable any person to follow up on the research to be done

# Licensing

- It should be made a crime to be in possession of GMO research related materials or to conduct a GMO research without a valid licence.
- Two licencing regimes are required.
  1. For an institution that will carry out GMO research and
  2. For every GMO research, field trial, general release, import, export, transit that will be done on Uganda territory

This would enable better regulation and monitoring

# Licensing

- For every licence to do a GMO Activity, there should be
  1. An EIA done before the granting a licence
  2. A social Impact Assessment
  3. Consultation of the Community

All stages of the licence need consulting the community



# Lab standards and biosafety

- The Bill is silent on laboratory standards and GMO safety. Laboratory standards are important for any kind of research and there is need to apply the highest possibly safety standards
- There is a proposal to provide for lab standards. However moving forward the country will need a law on Biosafety that will cover aspects of technology and biosafety engineering in Uganda

# Emergency plans

- The Bill provides for emergency plans in case of accidents but does not give responsibility to person doing research to do good of what was damaged.
- The Bill also does not look at situations where the person doing research is bankrupt or by some reason is unable to do good to the damage caused
- We are proposing giving powers to the authority to order a person to clean environment in case of damage
- We are proposing the authority to be given powers to order for payment in escrow for likely damage

# Accidents

- Provisions on accidental release are weak in as far as they look at accident as opposed to the legal standard of negligence.
- We are recommending that the authority investigates every accident and in case it establishes cases of accident, it should take appropriate action. All forms of accidents (other than act of god) should be punished in criminal law and under the law of negligence

# GMO Labeling

- The Bill does not provide for GMO Labeling. This would be important such that consumers are aware of what they are buying before making a decision
- We are proposing that every GMO product, garden, laboratory, etc. be marked to give informed consent to consumers

# Declaration of GMO Free area

- The Bill is silent on declaration of a GMO Free area where any part of Uganda can be declared a GMO free area for purposes of preserving the ecosystem or the genes.
- We are proposing a minister to have powers to declare any part of Uganda as a GMO free area
- We are also proposing that the community can apply to have an area declared a GMO free area

# Local content

- The Bill is silent on use and development of local technologies
- We are proposing that for every research application there must be participation of Ugandans
- Ugandans must at least be part of the top researchers in every research (50%)

# Patenting food products

- The Bill is silent on patents and patenting of food products. This has an effect of making farmers dependent on GMO companies.
- We are proposing that NO patent shall be allowed for food products made from GMOs
- The government will have a right of to access, use and distribute (freely) any GMO product developed in Uganda

# National gene bank

- The Bill is silent on the establishment of the National Gene bank. Whereas NARO under agricultural laws is meant to establish a gene bank, the present gene bank (Entebbe Botanical Gardens) and the farms ran by NAGRIC lack both the capacity and the funds to run a world class gene bank.



# Ban on terminator gene technology

- The Bill is silent on use and development of Genetic use restriction technology (GURT), terminator technology or suicide seeds.
- We should note that many scientists claim that this technology has been stopped in many parts of the country and may not be developed. However we need to restrict it in case it is developed.
- We are proposing a total ban on use of terminator gene technologies or terminator seed in Uganda. The Bill therefore should pronounce itself on this

